

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7 are drawn to compounds and compositions.

Group II, claim(s) 8-15, 23 and 24 are drawn to method of use.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The agents of the claims lack special structural element qualifying as special technical feature that defines a contribution over the prior art. The agents are related to benzo- derivatives which do not define a contribution over the prior art. WO 95/01338 teaches the use of benzo-derivatives as an inhibitor of PDE activity (Formula I and abstract). Therefore, unity of invention is lacking and restriction of the invention in accordance with the rules of unity of invention is proper.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

In Group I, claim 5, election of a single compound (or set of compounds which fall in the same group) is required including an exact definition of each substitution on the base molecule (structures defined) wherein a single member of each substituent group or moiety is selected. For example, in claim 5, when the base molecule has substituent groups R^1 and R^2 where R^1 and R^2 is recited to be any one of specific group like methyl or ethyl etc., Also, in Group I, Claim 1-4, elect one resultant concentration of the agent in the lung tissues like 350 times or 500 times.

If Group II is elected, claim 12, election of a single compound (or set of compounds which fall in the same group) is required including an exact definition of each substitution on the base molecule (structures defined) wherein a single member of each substituent group or moiety is selected. For example, when the base molecule has substituent groups R^1 and R^2 where R^1 and R^2 is recited to be any one of specific group like methyl or ethyl etc., Also in Group II, claim 8-11, elect one resultant concentration of the agent in the lung tissues like 350 times or 500 times.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Group I, claims 1-7
Group II, claims 8-15, 23 and 24.

The following claim(s) are generic: Group I, claim 7, Group II, 15, 23 and 24.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The agents related to benzo-

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derivatives and heterocyclic derivatives have already been described in the art as PDE inhibitors. (J. Pharm. Exp. Ther. 2001 297 280-290. Page 281, column, 2nd paragraph, p285, figure 1). The substituents on the formula I differ vastly and when taken as a whole result in different compounds. Accordingly the claims do not provide a new inventive concept over the prior art and thus lack unity of invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

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are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MANU MANOHAR whose telephone number is (571)270-5752. The examiner can normally be reached on Mon - Thu 9.00AM to 4.00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, PATRICK Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
Art Unit 4161

MM

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